

K081679

AUG 20 2008

**Summary of Safety and Effectiveness**Date: August 4, 2008Manufacturer:

Encore Medical, L.P.  
9800 Metric Blvd  
Austin, TX 78758

Contact Person:

Tiffany Hutto  
Manager, Regulatory Affairs  
Phone: (512) 834-6255  
Fax: (512) 834-6313  
Email: Tiffany\_Hutto@encoremed.com

Product	510(k) Number, Clearance Date, Classification	Product Code
Revelation® Hip Stem	K973683 - December 19, 1997 Class II	LPH, KWZ
Linear® Hip Stem	K974294 - January 12, 1998 Class II	LPH, LZO, KWZ

Product Code	Regulation and Classification Name
LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. per 21 CFR 888.3353
KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310

Description: The modification consists of an additional method of porous coating currently conducted on the hip devices listed above.

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

Both the Revelation and Linear hip stems are designed for a cementless application.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Encore Medical, L.P.  
% Ms. Teffany Hutto  
Manager, Regulatory Affairs  
9800 Metric Boulevard  
Austin, Texas 78758

**AUG 20 2008**

Re: K081679

Trade/Device Name: Revelation® Hip Stem & Linear Hip Stem

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: II

Product Code: LPH, LZO, KWZ

Dated: August 4, 2008

Received: August 6, 2008

Dear Ms. Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

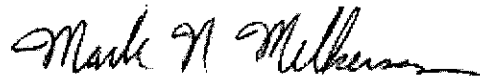
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Teffany Hutto

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K081679

Device Name: Revelation® Hip Stem & Linear Hip Stem

Indications for Use:

**Revelation® Hip Stem & Linear Hip Stem  
Indications for Use**

*Joint replacement is indicated for patients suffering from disability due to:*

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

These devices may also be indicated in the salvage of previously failed surgical attempts.

Both the Revelation and Linear hip stems are designed for a cementless application.

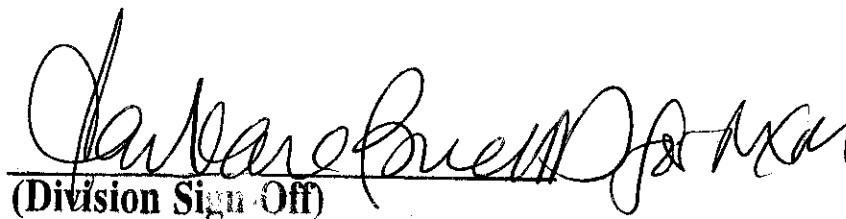
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRII, Office of Device Evaluation (ODE)

  
(Division Sign Off)

**Division of General, Restorative,  
and Neurological Devices**

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